Introduction

> The patient who is armed with information, who wants to ask questions, sometimes difficult and awkward questions, should be seen as an asset in the process of care and not an impediment to it.
>
> Sir Liam Donaldson, the Chief Medical Officer (CMO).[1]

In recent years the healthcare professions have been rocked by a number of high-profile scandals including the murderous activities of Harold Shipman and Beverly Allitt, the issue of organ retention and the problems of paediatric cardiac surgery at the Bristol Royal Infirmary (BRI).[2] In addition to these, the cost of clinical negligence litigation and adverse events in general have further focused the government's attention on healthcare practice.[3] The BRI Inquiry's remit included making recommendations to improve the quality of care in the NHS, with patient-centred care forming a bedrock principle underlying the recommendations.[4]

A crucial part of developing a patient-centred service was the need to '[encompass] the notions of respect for and honesty towards patients'.[5] Thus, not only was it important to focus on the mechanics of healthcare but also on the attitudes of the healthcare professionals. For the Inquiry the way forward was to encourage a partnership between the professionals and the patients.[6] It noted that, while healthcare professionals were in general dedicated to the good of the patient, there was a persistent and entrenched culture of paternalism that tended to exclude

[1] Speaking at the 2nd National Service Delivery and Organisation Conference (2003).
[2] I. Kennedy, *Learning from Bristol: The report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984–1995*, Cm 5207 (2001).
[3] See Chief Medical Officer, *An Organisation with a Memory* (London: Department of Health, 2000). In 2001, the National Audit Office (NAO) reported a seven-fold increase in costs since 1995–6: NAO, *Handling Clinical Negligence Claims in England*, HC 403 Session 2000–1 (2001), p. 1.
[4] Kennedy, *Learning from Bristol*, Chapter 21, paras. 1, 9.
[5] *Ibid.*, para. 14. [6] *Ibid.*, para. 23.

patients by limiting information and discouraging them from asking questions.[7]

A whole chapter of the final report was devoted to developing a culture of respect and honesty.[8] It began with a summary of the problems encountered at the BRI, which included a closed culture of paternalism, with patient communication delegated to junior members of staff. The Inquiry emphasised the importance of providing patients and their families with information and support. It suggested that the solution to the endemic paternalism was to redefine the professional–patient relationship as one of partnership 'involving patients, wherever possible, in decisions about their treatment and care'.[9] This approach to respect, information and partnership was something that the Government had already committed to.[10] Furthermore, in submissions to the Inquiry, professional bodies, such as the Royal College of Surgeons and the Royal College of Nursing, also acknowledged the importance of partnership.[11]

The Inquiry's concern for involving patients in treatment decisions gave rise to four key principles regarding information disclosure:[12]

- trust requires an attitude of openness;
- this in turn requires the honest and frequent provision of information;
- this is particularly relevant to information concerning risk and uncertainty; and
- information disclosure should be seen as 'a process and not a one-off event'.

In addition to the problems with a paternalistic approach to information, the Inquiry was also critical of the predominantly functional approach to consent. It emphasised that patients had a right to information and to choose whether or not to consent. For the Inquiry, patient choice was the guiding principle.[13]

The Department of Health (DH) responded by acknowledging a commitment to 'develop an NHS where there is a culture of openness and honesty . . . and where patients and staff work in genuine partnership'.[14] Thus, the DH included in their reform programme 'a consent

[7] *Ibid.*, Chapter 22, para. 17. [8] *Ibid.*, Chapter 23. [9] *Ibid.*, para. 2.
[10] Department of Health, *Patient and Public Involvement in the New NHS*, Health Service Circular: HSC (99) 210 (1999).
[11] Kennedy, *Learning from Bristol*, Chapter 23, para. 14. [12] *Ibid.*, para. 18.
[13] *Ibid.*, para. 45.
[14] Department of Health, *Learning from Bristol: The Department of Health's response to the report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984–1995*, Cm 5363 (2002), Executive Summary, para. 2; see also para. 1.4.

process which engages patients fully in decisions about their care'.[15] In fact, as the DH noted, it had already set up the Good Practice in Consent Initiative, as part of the implementation of the 2000 NHS Plan.[16] This involved establishing an advisory group and publishing guidance documents and a model consent form.[17] Apart from the symbolic importance of providing such guidance, the document provides helpful guidance on what is currently required by the law. For certain specific areas, such as consent to anaesthesia, the guidance is particularly helpful in clarifying who has responsibility. Unfortunately, however, it fails to venture far beyond that already required by the law. Nevertheless, it does serve to emphasise the importance of consent and it reinforces the commitment in the NHS Plan.

The commitment to patient-centred care is reinforced by the recent publication *Creating a Patient-led NHS*, which again indicates an intention to provide greater choice and information.[18] Other policies and initiatives, such as the Expert Patient Programme, the Patient Advice and Liaison Service,[19] the National Knowledge Service[20] and the development of information technologies such as HealthSpace (which will allow each patient internet space to record their care preferences), cement the Government's intention to empower patients.[21] In June 2004, the Secretary of State for Health stated:

> Patients' desire for high-quality personalised care will drive the new system. Giving people greater personal choice will give them control over these issues, allowing patients to call the shots about the time and place of their care, and empowering them to personalise their care to ensure the quality and convenience that they want.[22]

[15] *Ibid.*, Executive Summary, para. 13.
[16] www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/Consent/fs/en.
[17] Department of Health, *Good Practice in Consent Implementation Guide: Consent to examination or treatment* (2001).
[18] Department of Health, *Creating a Patient-led NHS: Delivering the NHS Improvement Plan* (2005), Chapter 1.
[19] Department of Health, *Learning from Bristol*, para. 2.12. See also the PALS website: www.pals.nhs.uk/.
[20] Department of Health, *Learning from Bristol*, para. 2.11. See also the dedicated website: www.nks.nhs.uk.
[21] Department of Health, *NHS Improvement Plan 2004: Putting people at the heart of public services*, Cm 6268 (2004), Executive Summary, para. 12. This commitment is reinforced by the 2008/9 *Operating Framework for the NHS in England*, available at www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_081094.
[22] The Rt Hon. John Reid MP, 'Building on the best – An NHS for the future' (2004), available at www.dh.gov.uk/en/News/Speeches/Speechlist/DH_4087161.

However, without suitable legal protection, these political intentions may provide less than they promise.[23] Furthermore, if patients are to be given choices to enable them to 'ensure the quality' of their decisions, then it is important that they are supported in their decision-making so as to prevent the provision of choice simply being used as a way of transferring responsibility to the patient. If patient choice is genuinely intended to enhance the patient's care then it must be supported by an intention to promote the patient's ability to make good decisions.

All healthcare interventions take place in the context of professional–patient contact making the professional–patient relationship – however fleeting – a core feature of healthcare provision. If patient-centred healthcare is to mean anything beyond shallow consumerism and political spin the focus must be on the interactions between the professionals and the patients they are caring for. If consent is necessary for the justification of healthcare interventions then, provided it is given a sufficiently textured interpretation, consent – and the communicative processes that envelop it – should be seen as integral to the creation of a patient-centred system of healthcare. In the recent report examining the professional regulation of doctors, the CMO noted the importance of good communication skills and the need to treat patients with respect by supporting their involvement in making decisions about their care and medical treatment.[24] It therefore seems an appropriate juncture to go back to square one and re-examine the law and ethics of consent to healthcare and the competent adult.

The book grew out of my Ph.D. thesis and is largely written in a way that reflects the journey I travelled in constructing the model of relational consent used as a yardstick to measure the acceptability of the current legal regulation. Central to my argument is the insight that the way in which healthcare professionals approach consent reflects their approach to the patient more generally. As such, consent is central to the professional–patient relationship. I also rely on the assumption that competent patients are responsible agents who want to make good decisions. My final assumption in undertaking this exploration of consent is that responsible agents are equally deserving of respect.

While parts of the journey will inevitably be familiar to some, it should be helpful to those readers with less expert knowledge. Furthermore, it

[23] See A. Coulter, 'Whatever happened to shared decision-making?' (2002) 5 *Health Expectations* 185; B. Sang, 'Choice, participation and accountability: Assessing the potential impact of legislation promoting patient and public involvement in health in the UK' (2004) 7 *Health Expectations* 187, 190.

[24] Chief Medical Officer, *Good Doctors, Safer Patients* (London: Department of Health, 2006), p. xi, available at www.dh.gov.uk/en/Publicationsandstatistics/Publications.

should provide useful insights into how and why my model of consent evolved. To that end, I necessarily explore the writings of a selection of other commentators who have commented on consent and the moral concepts that influence the way consent works in practice. The aim, however, is to construct a coherent and useful model of consent that both remains true to its core theory and reflects the value of autonomy. This model may then be used to expose the deficiencies in the legal regulation of consent and provide some suggestions as to how those flaws might be remedied.

In the first part of the book I examine the moral basis of consent. I begin by exploring the meaning and importance of autonomy. Despite some recent challenges to the association between autonomy and consent,[25] if autonomy is seen as the right of moral agents to make self-regarding decisions the connection seems clear. The requirement for consent protects patients from paternalistic or other unjust actions that infringe their rights. While the rules implementing the requirement for consent may be criticised for failing to be sufficiently sensitive to a thick conception of autonomy,[26] this does not undermine the essential relationship between autonomy and consent. However, the healthcare professional's obligation to respect the patient's autonomy should not be examined in isolation from the professional's other duties. In Chapter 2 I therefore consider the relevance of beneficence, justice and virtue and I discuss how they may help to shape the extent of the healthcare professional's duty to respect the patient's autonomy. Then, in Chapter 3, I situate the debate within the context of the professional–patient relationship, which is important because consent always involves at least two parties and the rules necessarily depend on the context of the interaction between them.

In the last chapter of Part I of the book I explore the concept of consent. The approach I take in my analysis is necessarily based in the way others have used the concept. This deconstruction is an essential part of developing a meaningful and useful conception of consent. While analysing the concept I tease out the relevant attributes that reflect the pragmatic and moral aspects of consent to healthcare interventions. Bearing in mind the context of the professional–patient relationship, this allows me to develop a relational model of consent to healthcare interventions.

[25] See e.g. J. S. Taylor, 'Autonomy and informed consent: A much misunderstood relationship' (2004) 38 *The Journal of Value Inquiry* 383.
[26] O. O'Neill, *Autonomy and Trust in Bioethics* (Cambridge: Cambridge University Press, 2002), pp. 37–48.

In Part II, I examine the law's approach to consent. I analyse the law chronologically, which is important because it provides insights into the processes of the common law and the interaction between ethical theory and the legal regulation of medical practice. This highlights the problems faced in trying to develop an ethically nuanced standard through the courts.

In Chapter 5, I consider the legal regulation of consent in battery and negligence. As far as possible, I explicate the rules that the courts have developed, particularly those in relation to risk disclosure and the communicative aspects of consent. This necessarily requires a formal and detailed exposition of the leading cases, which then allows, in Chapter 6, a comparison of the legal model of consent with the relational model developed in Part I of the book. The chapter ends with a brief consideration of whether the common law could develop sufficiently to meet the criticisms of the current legal regulation, whether professional regulation could paper over the deficiencies or whether legislation is the most appropriate response.

In the final chapter I consider where the law could go in future. I begin revisiting the developments to date in the legal regulation of consent. This analysis focuses on the cycle of criticism and change allowed by the scope of the concepts of autonomy, rationality and consent. I then examine Manson and O'Neill's recent proposal for a shift from informed consent to their conception of a 'genuine consent'.[27] Given the influential status of Baroness Professor O'Neill it is plausible that Manson and O'Neill's model of 'genuine consent' could influence professional practice. As such, it seems the most likely theory of consent to affect how the common law may develop in future. It is, therefore, important to compare their model with the relational model constructed in Part I of the book. I argue that, while their model may be a valuable stage in the evolution of consent, it fails to provide sufficient support for good decision-making. Furthermore, if it were to be adopted under the current common-law system, the strengths of Manson and O'Neill's model may be undermined by reactive regulation and risk-management approaches that focus on the outcome rather than the process of disclosure. As an alternative I return to my argument that a relational model of consent should be implemented through legislation and I expand the model to illustrate how it may be successfully realised.

[27] N. C. Manson and O. O'Neill, *Rethinking Informed Consent in Bioethics* (Cambridge: Cambridge University Press, 2007); O. O'Neill, 'Some limits of informed consent' (2003) 29 *Journal of Medical Ethics* 4.

Part I

An ethical model

1 Autonomy

In the introduction I suggested that consent is predicated on autonomy. If one considers the role consent plays, which I will discuss in more detail in Chapter 4, the connection with autonomy seems apparent. It has not, however, gone unchallenged and I will address this later in the chapter.[1] Starting with the etymological derivation of autonomy, which comes from the Greek and means self-rule, both senses of consent – as a waiver of a right and as a negotiated agreement – depend on the patient's autonomy, at least in the sense of autonomy as self-determination. Consent raises issues of liberty, power, control and responsibility; all of which are also relevant to the importance of autonomy.[2] Because of this connection, it is essential to explore autonomy in some detail. This will allow the attributes of consent to be given more substance, which is a necessary part of determining the moral and legal duties that consent imposes on the healthcare professional. To explicate autonomy and its influence on consent I will explore the nature, value and limits of autonomy. I will then examine the nature of the connection between consent and autonomy.

The nature of autonomy

Various senses and conceptions of autonomy have been expounded.[3] If there are real differences between these approaches to autonomy then the conception adopted may affect the obligations arising from the patient's right of consent. Rather than simply assert my own version of autonomy, recognising these competing conceptions makes it necessary to consider the different views. It seems appropriate to begin with the list

[1] Manson and O'Neill, *Rethinking Informed Consent*, pp. 16–22; Taylor, 'Autonomy and informed consent'.
[2] See e.g. K. Lehrer, 'Reason and autonomy' (2003) 20 *Social Philosophy and Policy* 177.
[3] J. Bergsma and T. Thomasma, *Autonomy and Clinical Medicine: Renewing the health professional relation with the patient* (Dordrecht: Kluwer Academic Publishers, 2000), pp. xiii–xiv.

that Gerald Dworkin constructed in his classic exposition of autonomy, which includes autonomy as liberty or freedom to act; as dignity; as 'freedom of the will'; as 'independence'; and as 'critical reflection'.[4] The list may be expanded to include: 'self-mastery; choosing freely; choosing one's own moral position and accepting responsibility for one's choice';[5] 'self-control' and 'self-determination'.[6]

It is apparent from this list that one of the problems with autonomy is that there are almost as many different conceptions as there are commentators writing on the subject. However, this does not mean that there is no single concept and, rather than simply being alternative concepts of autonomy, the various uses of autonomy reflect an amalgam of the different aspects and senses of autonomy. Approached in this way, it may be possible, in the context of healthcare, to determine a core concept with a choice of conceptions. The most meaningful conception may then be determined from the value reflected in the core concept and the context of its application.

The core concept is revealed by the etymology of the word itself. As noted above, autonomy literally means self-rule and this is the central feature of all the various different conceptions. This central notion depends on the claim that we are free-willed agents capable, at least, of making decisions. I will discuss the problem of determinism later, but for now I will assume that adult human beings ordinarily are capable of self-determination. Where rationality is required then this capacity may vary greatly between individuals. Furthermore, the psychological predisposition to exercise the ability may also vary (see p. 91). However, the capacity for self-determination is a necessary feature of agency, which is crucial to the justification provided by consent.

This capacity for self-determination means that, at its core, autonomy is a natural kind concept. However, the different conceptions that have been argued for are, to a greater or lesser extent, social constructs that rely on a mixture of biological and normative claims. The normative claims essentially depend on the type of society, or more specifically to the present discussion, the type of healthcare service that the author is arguing for. A libertarian will construct a different conception of autonomy to the liberal and the liberal view will differ from the communitarian.[7] These fundamentally different perspectives on autonomy

[4] G. Dworkin, *The Theory and Practice of Autonomy* (Cambridge: Cambridge University Press, 1988), p. 6.
[5] R. Faden and T. L. Beauchamp, *The History and Theory of Informed Consent* (New York: Oxford University Press, 1986), p. 7.
[6] O'Neill, *Autonomy and Trust*, p. 22.
[7] A. Maclean, 'Consent and sensibility' (2005) 4 *International Journal of Ethics* 31.

mean that it is unlikely that the debate will ever be fully resolved in favour of one conception over another. This is not, however, a problem. In fact, the opposite is true since these different approaches provide the basis for the criticism necessary to a vibrant democratic politic.[8] The caveat is, of course, that unless we are content with incoherent and inconsistent rules, the law, and indeed professional ethical guidelines, must choose one version over another. This choice will not be fixed for all time, but will be subject to the continuing critique of others with differing views. Nevertheless, a conception of autonomy should be selected with the preferred choice determined by the type of healthcare system we want.

Although there are many different conceptions of autonomy they can be broadly grouped into three categories. The libertarian approach is to see autonomy simply as self-determination. The liberal view requires the inclusion of rationality. The communitarian approach would be to require autonomy to also have substantive moral content. While it is possible to discern these three broad characterisations of autonomy this is not to suggest that they are discrete. In particular the inclusion of a requirement for rationality adds another dimension that it is susceptible to one's political persuasion and allows for a complex and nuanced approach to autonomy. The different nuances at play allow the conception of autonomy to be seen as existing on a continuum that spans from the extreme libertarian view of autonomy as atomistic, independent self-determination to the communitarian extreme in which the importance of individual autonomy is subjugated to the needs and interests of the community. Between these caricatured approaches lie many more plausible conceptions. In the subsequent discussion I will begin to construct an argument setting out the conception of autonomy that should ground the legal regulation of consent.

Autonomy as self-determination

In addition to the different conceptions of autonomy, the concept is further complicated by the different senses in which autonomy may be used. For example, the term may be employed to refer to an individual's capacity to 'think, decide and act'.[9] Alternatively, it may be used to

[8] A. Maclean, 'Magic, myths and fairytales: Consent and the relationship between law and ethics', in M. Freeman (ed.) *Law and Bioethics*, *Current Legal Issues*, vol. 11 (Oxford: Oxford University Press, 2008), Forthcoming.
[9] R. Gillon, *Philosophical Medical Ethics* (Chichester: John Wiley & Sons, 1985), p. 60.